



Establishing a No-Fault Compensation System to Replace Failure-to-Warn Product Liability Claims Against Prescription Drug Manufacturers

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**Establishing a No-Fault Compensation System to
Replace Failure-to-Warn Product Liability Claims
Against Prescription Drug Manufacturers**

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ABSTRACT

In 1986, Congress passed the National Childhood Vaccine Injury Act, which established a no-fault compensation system to provide money to people who are injured by vaccines. The major impetus behind this Act was the soaring cost of tort litigation and damages awards imposed on vaccine manufacturers, which was causing many manufacturers to stop producing vaccines altogether. The resulting vaccine shortages threatened the public health of the country. In recent years, manufacturers of prescription drugs have paid large damages awards and legal fees that are akin to those costs borne by vaccine manufacturers in the 1970s and early 1980s. Pharmaceutical manufacturers can be liable for billions of dollars if patients who take a drug suffer an unexpected adverse event that was not discovered during clinical trials. The uncertainty about the extent of liability a manufacturer may face for a particular drug is causing many manufacturers to remove beneficial drugs from the market or to forego drug development altogether. As a result, Congress should establish a no-fault compensation system to replace failure-to-warn claims against prescription drug manufacturers. Such a scheme would significantly reduce the incredible costs that the current drug product liability system imposes on drug manufacturers. At the same time, patients who take a prescription drug and suffer a serious injury that was not foreseen by the drug manufacturer or the FDA will be compensated, so long as they can prove that the drug was the cause of their injury. The National Vaccine Injury Compensation Program is an excellent model that Congress can adapt to meet the needs of participants in the market for prescription drugs.

***Establishing a No-Fault Compensation System to Replace Failure-to-Warn
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I. Introduction

In 1986, Congress passed the National Childhood Vaccine Injury Act.¹ The Act established a no-fault compensation system – the National Vaccine Injury Compensation Program – that provides money to people who are injured by vaccines. Before the program was

¹ 42 U.S.C. §§ 300aa-1 et. seq.

implemented, an individual who was injured by a vaccine could sue the vaccine's manufacturer under the theory that the vaccine was defectively designed or that the manufacturer had failed to warn the public about the risks associated with vaccination. In the 1970s and 1980s, vaccine manufacturers paid billions of dollars in compensatory and punitive damages awards and legal fees. The high costs of tort litigation imposed on vaccine manufacturers caused many manufacturers to stop producing vaccines altogether, leading to dangerous vaccine shortages that threatened the public health of the country.

To limit soaring legal costs and ensure that the United States receives a sufficient supply of vaccines, Congress established a no-fault compensation system that is administered by the Department of Health and Human Services, the Department of Justice, and the Court of Federal Claims. Vaccine manufacturers contribute to a trust fund by paying a tax on each vaccine that is administered. If a person receives a vaccine that is covered by the program and is injured within a certain amount of time after the vaccine is administered – or can prove that the injury was caused by the vaccine – that person is eligible to receive money from the trust fund to cover medical expenses and other damages. A special master at the Court of Federal Claims evaluates petitions for compensation and makes a decision about the amount of money to be awarded; the claimant can appeal this decision to the Court of Appeals for the Federal Circuit and then to the Supreme Court. Since the program started awarding money in 1988, \$2,281,706,685.32 has been disbursed to petitioners and \$89,108,361.76 has been paid to cover attorney's fees and other legal costs.²

In recent years, manufacturers of prescription drugs have paid soaring damages awards and legal fees that are akin to those costs borne by vaccine manufacturers before the National

² NATIONAL VACCINE INJURY COMPENSATION PROGRAM: DATA & STATISTICS, <http://www.hrsa.gov/vaccinecompensation/data.html> (last updated May 1, 2012).

Vaccine Injury Compensation Program was established. Patients who suffer an unexpected adverse event after taking a drug can sue the drug's manufacturer on the theory that the manufacturer failed to provide an adequate warning about possible side effects of the drug. Even when a drug has been approved by the Food and Drug Administration (FDA), a manufacturer can be liable for billions of dollars if patients suffer injuries that were not discovered during clinical trials. This was the case with the fen-phen "diet drug," which ended up costing pharmaceutical manufacturer Wyeth \$16 billion over ten years of litigation.³ The uncertainty about the extent of liability a manufacturer will face for a particular drug is causing many manufacturers to forego drug development altogether or to remove beneficial drugs from the market.

Several scholars have proposed replacing failure-to-warn claims with a no-fault compensation system modeled after the National Vaccine Injury Compensation Program. Like the vaccine program, this system would function by using a tax on prescription drugs to award money to patients who suffer unexpected adverse events after taking a drug. This new scheme would help ensure that drug manufacturers are not deterred from investing in new and innovative drugs for fear of the crippling legal costs that may result under the current tort system.

This paper argues that Congress should establish a no-fault compensation system to replace failure-to-warn claims against prescription drug manufacturers. In Part II, it evaluates the current system of drug product liability, which comprises state-law tort claims for manufacturing defects, design defects, and inadequate warnings of potential side effects. Part III describes the National Vaccine Injury Compensation Program and evaluates some of the program's successes and failures since its inception in 1986. Part IV proposes the Prescription Drug Injury

³ Anita Bernstein, *Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation*, 15 J.L. & POL'Y 1051, 1054 (2007).

Compensation Program, modeled after the vaccine program, which would replace state-law failure-to-warn claims against prescription drug manufacturers. Part V concludes.

II. Evaluating the Current Drug Product Liability System

A. Drug Product Liability: Causes of Action

There are three causes of action that someone who is injured by a prescription drug can bring against the drug's manufacturer. First, the injured plaintiff can claim that the drug had a manufacturing defect.⁴ If the plaintiff can prove this claim, the drug manufacturer is held strictly liable for the defect.⁵ Second, the plaintiff can argue that the drug is defective in design.⁶ Both manufacturing defect and design defect claims are relatively rare and uncontroversial.⁷ The bulk of drug product liability litigation involves the third possible claim against drug manufacturers: the manufacturer failed to provide an adequate warning about foreseeable risks associated with the drug.⁸ When a plaintiff brings a failure-to-warn lawsuit against a drug manufacturer, there are three major issues that must be resolved by the court: 1) whether the drug actually caused the plaintiff's injury; 2) whether the manufacturer had sufficient knowledge about the risk of that injury such that it had a duty to warn; and 3) whether the warnings provided were adequate to satisfy the manufacturer's duty.⁹

⁴ Restatement (Third) of Torts: Products Liability § 2. A product "contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product." *Id.*

⁵ *Id.*

⁶ Restatement (Third) of Torts: Products Liability § 2. A product "is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor . . . and the omission of the alternative design renders the product not reasonably safe." *Id.*

⁷ Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 470, 472 (1997).

⁸ Restatement (Third) of Torts: Products Liability § 2. A product "is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor . . . and the omission of the instructions or warnings rendered the product not reasonably safe." *Id.*

⁹ Green, *supra* note 7, at 473.

B. Cost-Benefit Analysis of the Drug Product Liability System

The drug product liability system should only be replaced with a no-fault compensation scheme if the system's costs outweigh its benefits. At the outset of this analysis, it is important to note the difficulty of quantifying the costs and benefits of the current system.¹⁰ Individual drug manufacturers are usually unwilling to disclose the details of their legal expenses for fear that publicizing this information would encourage new suits or increase future settlement demands.¹¹ In addition, many jury awards are reduced on appeal, and settlements between drug manufacturers and injured plaintiffs are frequently sealed.¹² Therefore, it is very difficult to determine how much money pharmaceutical companies spend to defend drug product liability suits. On the benefits side, it is impossible to calculate the extent to which drugs are safer and more effective as a result of the tort system. It is also difficult to determine how many patients who are injured by prescription drugs actually receive compensation from the drug manufacturer. Even so, it is worth considering and attempting to weigh the costs and benefits of the drug product liability system to assess the strength of the case for reform.

1. Direct Costs: Litigation Expenses and Damages Awards

Drug product liability lawsuits – and failure-to-warn claims in particular – have cost some pharmaceutical manufacturers billions of dollars and many years of litigating and negotiating settlements in courts all over the country. For example, Eli Lilly's drug Zyprexa, used to treat schizophrenia and bipolar disorder, was the target of many lawsuits brought by plaintiffs claiming that they developed diabetes or other blood sugar disorders after taking the

¹⁰ Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199, 229 (1992).

¹¹ *Id.* at 229 & n.205.

¹² *Id.*

drug.¹³ By 2007, Eli Lilly had agreed to pay \$1.2 billion to settle claims with 28,500 people who were injured by the drug.¹⁴ Vioxx, Merck's wildly popular arthritis drug, was withdrawn from the U.S. market after patients taking the drug began experiencing higher rates of heart attack and stroke.¹⁵ In 2008, Merck reached a \$4.85 billion settlement agreement to compensate injured patients.¹⁶ The most extreme example of direct costs of drug product liability litigation is the diet drug phen-fen, which kept its manufacturer Wyeth in court for over a decade after patients suffered cardiac injuries that had not been identified as a risk of taking the drug for an extended period of time.¹⁷ By the time most of the claims had been resolved, Wyeth had spent more than \$16 billion.¹⁸

2. Indirect Costs: Uncertainty and Overdeterrence

In addition to direct costs such as money and time spent litigating that pharmaceutical manufacturers face under the current system of drug product liability, there are many indirect costs that are more difficult to quantify. The most significant indirect cost is uncertainty; it is frequently difficult or impossible for a drug manufacturer to predict how much money it will have to spend on tort litigation for a particular drug. For some drugs, litigation costs may turn out to be very low, but for others that have unexpected side effects, damages awards and settlement payments might be astronomical. Even if a pharmaceutical company attempts to calculate ex ante the financial burden of hypothetical failure-to-warn claims for a specific drug, various aspects of the tort liability system make it nearly impossible to come up with an accurate estimate. For example, jury awards in tort cases vary immensely because “jurors exercise substantial leeway in

¹³ Bernstein, *supra* note 3, at 1054.

¹⁴ Alex Berenson, *Lilly Settles with 18,000 Over Zyprexa*, THE NEW YORK TIMES, Jan. 5, 2007, available at <http://query.nytimes.com/gst/fullpage.html?res=9f00e5db1430f936a35752c0a9619c8b63>.

¹⁵ Bernstein, *supra* note 3, at 1054.

¹⁶ VIOXX SETTLEMENT UPDATE, <http://www.officialvioxxsettlement.com/> (last visited May 2, 2012).

¹⁷ Bernstein, *supra* note 3, at 1054.

¹⁸ *Id.*

determining damages, which in turn permits variation in outcomes of similar cases.”¹⁹ Not only are most jurors ill-equipped to calculate damages properly, nearly all of them are unqualified to resolve complex scientific issues of causation.²⁰ A juror’s task is made all the more difficult by the fact that she has to rely on the testimonies of competing expert witnesses who frequently present evidence and opinions of dubious scientific validity.²¹

When the uncertainty about the extent of liability for a particular drug is compounded with uncertainty about whether a drug in the R&D pipeline will successfully treat a disease, several undesirable consequences may result. First, pharmaceutical manufacturers might decide to forego drug development altogether.²² The chilling effect of uncertainty therefore causes the benefits of new and effective drugs to be lost to society.²³ One significant example of this was Oculinum, an experimental drug undergoing clinical trials in the mid-1980s. The drug showed incredible promise as a treatment for blepharospasm, a condition characterized by eyelid muscle spasms that clamp the eyelids closed for several minutes.²⁴ In 1984, however, Oculinum’s manufacturer decided to halt clinical testing because the company could not obtain affordable liability insurance for the drug.²⁵

More recently, there have been striking examples of drug shortages and the consequences of such shortages for patients. In 2003, a director of pharmacy services at the New Jersey Hospital Association explained that hospitals frequently face shortages of injectable anesthetics,

¹⁹ Alexandra D. Lahav, *The Case for “Trial by Formula,”* 90 TEX. L. REV. 571, 584 (2012).

²⁰ Jackson, *supra* note 10, at 232-33.

²¹ *Id.*

²² Green, *supra* note 7, at 467.

²³ See Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION, 334 (Peter W. Huber & Robert E. Litan eds., 1991).

²⁴ Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 774 (1990).

²⁵ *Id.* According to a *Time* article published in 1984, “nationwide testing has been halted because the manufacturer says he is no longer able to find an insurance company that will sell him affordable liability insurance. . . . [I]nsurers are afraid they will be hit with huge damage suits if any untoward side effects occur.” *Eye Misery: Insurance Loss Halts Drug Test*, TIME, Oct. 27, 1986, at 71.

painkillers, antibiotics, and steroids.²⁶ He complained that “at any given time, it seems there are about four dozen drug items that are near-impossible to get.”²⁷ The consequences of drug shortages were dire for three patients being treated for bacterial meningitis in San Francisco; they died after a local pharmacy prepared a contaminated drug mixture as a substitute for a steroid that was temporarily unavailable.²⁸ Medical professionals have also expressed concern about significant drug shortages in specific markets, such as the market for drugs used to treat illness and disease in children.²⁹ There are many factors that deter pharmaceutical manufacturers from producing drugs to treat children, including the level of liability exposure that might result if a drug unexpectedly caused children to suffer serious adverse events.³⁰

A second consequence of uncertainty and overdeterrence is that manufacturers who do develop new drugs are more likely to test those drugs more rigorously over a longer period of time, thereby delaying the availability of the drug to patients.³¹ A third consequence is that manufacturers are likely to increase the cost of a prescription drug in order to create a financial buffer in case the drug ends up costing the manufacturer billions of dollars in tort damages.³² The increasing cost of liability insurance may also incentivize drug manufacturers to raise the price of prescription drugs.³³

²⁶ Paula Jacobi, *Pharmaceutical Tort Liability: A Justifiable Nemesis to Drug Innovation and Access?*, 38 J. MARSHALL L. REV. 987, 992 (2005).

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.* Other factors that deter drug manufacturers from producing drugs for children are the small size of the pediatric market (since children are a relatively healthy sector of the population) and public sensitivity associated with using children as test subjects in clinical trials. *Id.*

³¹ Green, *supra* note 7, at 467.

³² Jackson, *supra* note 10, at 205.

³³ One example in the context of vaccines is demonstrated by the increasing price of the diphtheria-tetanus-pertussis (DPT) vaccine, which cost 11¢ in 1982 and \$11.40 in 1986. Eight dollars of the money received for each dose in 1986 went to the manufacturer’s liability insurance. *Id.*

A fourth consequence of uncertainty is that beneficial drugs are withdrawn from the market.³⁴ One prominent example of this is the drug Bendectin, which was manufactured by Merrell Dow and approved by the FDA to treat morning sickness in pregnant women.³⁵ In the early 1980s, Merrell Dow had to defend over 2,100 product liability lawsuits after allegations surfaced that Bendectin caused birth defects in children born to mothers taking the drug.³⁶ Although the FDA conducted an investigation of Bendectin's safety, it failed to reveal any evidence that the drug was dangerous to unborn children.³⁷ Even the scientific community could find no causal connection between Bendectin use and fetal deformity.³⁸ Yet Merrell Dow had to defend numerous lawsuits targeting the drug, and the manufacturer agreed to a class action settlement of \$120 million. Ultimately, Merrill Dow decided to withdraw Bendectin from the market, and the drug's therapeutic advantages were no longer available to pregnant women.³⁹

In conjunction, these four consequences of uncertainty perpetrated by the current tort liability system lead to shortages in supplies and suppliers of pharmaceuticals.⁴⁰ Fears about shortages in vaccine supply and suppliers were a major impetus behind the National Childhood Vaccine Injury Act.⁴¹

3. *Costs Imposed by Recent Federal Preemption Jurisprudence*

Recent court decisions dealing with the issue of federal preemption of state tort claims only strengthen the case for a no-fault scheme to compensate patients who are injured by prescription drugs. Most significantly, in 2009, the Supreme Court decided *Wyeth v. Levine*.⁴²

³⁴ Green, *supra* note 7, at 467.

³⁵ Jacobi, *supra* note 26, at 990.

³⁶ *Id.*

³⁷ *Id.* at 991.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ Green, *supra* note 7, at 467.

⁴¹ See *infra* Part III.A.

⁴² 555 U.S. 555 (2009).

Plaintiff Levine was injured by a drug that was administered intravenously, and she brought suit against the drug's manufacturer for failing to provide adequate warnings about the significant risks of intravenous administration.⁴³ Pharmaceutical manufacturer Wyeth, however, had complied with all FDA labeling requirements for the drug.⁴⁴ Wyeth argued that Levine's state-law claims should be preempted because it would be impossible for the drug manufacturer to comply with both the state-law duties underlying those claims and federal labeling duties imposed by the FDA.⁴⁵ The Supreme Court rejected this argument and held that Levine's failure-to-warn claim was not preempted by federal law.⁴⁶

The Supreme Court's holding in *Wyeth* solidifies the significant financial burden that a drug manufacturer faces if patients suffer an adverse event that is not adequately described on the drug's label. After this decision, even if a drug manufacturer complies with all FDA labeling requirements, the manufacturer must still comply with every state-law requirement, or it might be on the hook for billions of dollars. This financial burden could have a significant chilling effect on drug manufacturers' willingness to develop and sell innovative new drugs. If state-law failure-to-warn claims were replaced with a no-fault compensation system, drug manufacturers would not bear the burden of paying massive compensatory and punitive damages for adverse events that the FDA does not require to be described on the drug's label.

Two years later, in 2011, the Supreme Court again faced the issue of federal preemption of state tort claims. In *PLIVA, Inc. v. Mensing*, plaintiffs had taken the generic version of a drug for several years and subsequently developed tardive dyskinesia.⁴⁷ They sued the generic manufacturer of the drug in state court for failing to provide adequate warning labels. The

⁴³ *Id.* at 559-60.

⁴⁴ *Id.* at 562.

⁴⁵ *Id.* at 563.

⁴⁶ *Id.* at 581.

⁴⁷ 131 S. Ct. 2567 (2011).

manufacturer argued that federal statutes and FDA regulations should preempt the state tort claims because they require the generic drug to have the same safety and efficacy labeling as the brand-name drug.⁴⁸ The Supreme Court agreed with the manufacturer, holding that federal law preempts state laws imposing the duty to change a drug's label upon generic drug manufacturers.⁴⁹

The outcome of the *Mensing* case provides further evidence that the current system of drug product liability should be reformed. After this decision, if a patient takes the brand-name form of a drug, that patient may bring state-law tort claims against the manufacturer for failing to provide adequate warnings about a particular adverse event. But if a patient takes the generic form of that drug, he or she cannot sue the drug's manufacturer in state court. The patient who takes the generic form of the drug cannot sue the manufacturer of the branded drug either, because the element of causation is missing; the branded drug did not *cause* the patient's injuries. Patients who took the generic drug are therefore left without a significant avenue of recovery that is available to patients who took the brand-name version of the same drug. A no-fault compensation scheme that preempts failure-to-warn claims against both generic and branded manufacturers would eliminate this disparity and provide relief to all patients who are injured by different versions of the same drug.

4. *Benefits*

It is apparent that the current system of drug product liability imposes significant costs on society. But there are two major ways that the system might benefit society.⁵⁰ First, and most importantly, the system might enhance drug safety and effectiveness beyond that provided by

⁴⁸ *Id.* at 2573.

⁴⁹ *Id.* at 2581.

⁵⁰ Jackson, *supra* note 10, at 229.

federal regulation and oversight.⁵¹ Second, the system might efficiently spread the risk of drug-induced injuries by compensating those who are injured by prescription drugs.⁵²

Several scholars have argued that the tort system enhances drug safety over that achieved through FDA regulation alone. This is because a significant amount of critical information emerges about a drug's safety *after* it has been approved by the FDA and made available to the public.⁵³ There are several reasons why it is difficult for a drug manufacturer to uncover all of a drug's side effects during clinical trials.⁵⁴ For one, it is hard for the manufacturer to anticipate all of the side effects that a drug might cause and design a clinical trial to detect those effects.⁵⁵ In addition, if an adverse event is rare or only affects a certain subset of the population, it may not emerge in clinical trials that are conducted on a limited number of subjects.⁵⁶ As a result, many prescription drugs reach the market without warnings about adverse events that eventually begin to affect patients. The threat of drug product liability lawsuits therefore incentivizes pharmaceutical manufacturers to add additional warnings to drug labels as soon as they become aware of new side effects.⁵⁷ Even if the FDA resists a drug manufacturer's suggested label change, the manufacturer often takes an aggressive stance to ensure that the change is made; it is in the company's best interest to disseminate information about new risks that emerge as promptly as possible.⁵⁸

The tort system might also play a role in incentivizing pharmaceutical manufacturers to participate in the FDA's adverse event reporting system. The FDA requires drug manufacturers

⁵¹ *Id.*

⁵² *Id.*

⁵³ Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U. L.J. 163, 179 (1998).

⁵⁴ *Id.* at 180.

⁵⁵ *Id.* (quoting Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 496 (1997)).

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

to report serious Adverse Drug Reactions (ADRs) within fifteen days of the event being reported to the manufacturer.⁵⁹ Drug companies may fail to submit ADRs to the FDA out of a concern that profitable drugs will be pulled from the market.⁶⁰ However, the Fourth Circuit has held in a failure-to-warn action that a pharmaceutical manufacturer can be required to pay punitive damages for withholding ADRs from the FDA.⁶¹ According to one commentator, “the threat of punitive damages from thousands of litigants forces drug manufacturers to consider these litigation costs when deciding whether to investigate and report ADRs.”⁶² The more ADRs that are reported by drug companies, the more quickly the FDA will be able to identify harmful drugs and either warn consumers or remove the drugs from the market.

The tort system may also benefit society by efficiently spreading the risk of injuries caused by prescription drugs, products that have been deemed avoidably unsafe. According to this argument, the damages paid to plaintiffs who have been injured by prescription drugs are part of the cost of doing business for pharmaceutical manufacturers. Manufacturers pass on the costs imposed by the tort system to the public in the form of increased drug prices. If the system functions as it should, manufacturers are profitable and patients who suffer unexpected adverse events after taking a prescription drug are compensated for their injuries.

5. *Weighing the Costs and Benefits*

While some commentators believe it is a benefit that the tort system incentivizes pharmaceutical manufacturers to update drug labels as the company acquires new information about unexpected adverse events, others view this incentive as a cost of the system. Some

⁵⁹ 21 C.F.R. § 314.80 (2005). The FDA defines an ADR as “serious” if it results in “[d]eath, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.” *Id.*

⁶⁰ Anne Erikson Haffner, *The Increasing Necessity of the Tort System in Effective Drug Regulation in a Changing Regulatory Landscape*, 9 J. HEALTH CARE L. & POL’Y 365, 392 (2006).

⁶¹ *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1389 (4th Cir. 1995).

⁶² Haffner, *supra* note 60, at 394.

scholars who have argued for tort reform express concern that drug manufacturers flooding the FDA with requests for label changes – in hopes of avoiding failure-to-warn lawsuits – may discourage patients from using beneficial medical products.⁶³ In addition, tort liability claims against manufacturers place immense pressure on the FDA to re-label drugs or withdraw them from the market on the basis of anecdotal evidence.⁶⁴ While some drugs will be made safer by the drug product liability system, other drugs will be removed from the market before scientists have a chance to determine whether or not the drug is actually dangerous.

Although one of the purported benefits of the tort system is that it efficiently spreads the risk of dangerous drug products, there is evidence that the “vast majority of drug-induced injuries go uncompensated as a result of the rigors of the tort system.”⁶⁵ While some plaintiffs win “jackpot” awards, other plaintiffs whose claims are equally legitimate go without compensation entirely.⁶⁶ There are also many barriers that make it difficult for injured patients to enter the tort system in the first place. Someone who has been injured by a drug first has to recognize the causal relationship between the injury and the drug.⁶⁷ Then, the injured individual has to identify his legal privileges, meaning his right to sue the drug’s manufacturer to be compensated for the injury.⁶⁸ Finally, the individual has to find competent counsel to execute the lawsuit.⁶⁹ The tort system is not achieving its goal of efficient risk-spreading if consumers are paying exorbitant prices for drugs but are not being compensated when they get injured by those drugs.

⁶³ James R. Copland & Paul Howard, *In the Wake of Wyeth v. Levine: Making the Case for FDA Preemption and Administrative Compensation*, PROJECT FDA REPORT 2 (2009), available at http://www.manhattan-institute.org/html/fda_01.htm.

⁶⁴ *Id.*

⁶⁵ Jackson, *supra* note 10, at 234.

⁶⁶ Copland & Howard, *supra* note 63, at 11.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

Finally, it is important to consider the possibility of designing a different system to compensate injuries caused by prescription drugs that eliminates some of the costs of the tort system while retaining many of the benefits. The National Vaccine Injury Compensation Program attempts to strike a balance between compensating people who have been injured by a vaccine and incentivizing vaccine manufacturers to supply safe and effective products. Using the vaccine program as a model, Congress can design a no-fault compensation scheme that strikes this balance in the realm of prescription drugs.

III. The National Childhood Vaccine Injury Act and Other No-Fault Compensation Schemes

A. Why did Congress Pass the National Childhood Vaccine Injury Act?

Vaccination has been an important aspect of public health management in the United States since the beginning of the 19th century. In 1905, the Supreme Court decided *Jacobson v. Massachusetts* and upheld the authority of states to enforce compulsory vaccination laws.⁷⁰ By the time *Jacobson* was decided, many states already required children to be vaccinated before they entered public school. Today, immunizations against diphtheria, measles, rubella, and poliomyelitis are required for public school attendance in all states.⁷¹ Most states also require children to be vaccinated against tetanus, pertussis, and mumps.⁷²

Although it is rare for vaccines to cause serious injury or death, the sheer number of vaccines administered every year yield many children – and occasionally adults – who suffer complications as a result of vaccination.⁷³ During the 1970s and 1980s, an increasing number of injured people filed lawsuits against vaccine manufacturers, claiming that vaccines had been

⁷⁰ 197 U.S. 11 (1905).

⁷¹ Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 60 (1999).

⁷² *Id.*

⁷³ *Id.*

negligently manufactured or that vaccines had not been accompanied with adequate warnings about the risk of injury or death.⁷⁴ Many of these suits were incited by media hype about “scientific evidence” linking vaccines and serious injuries, such as the alleged connection between the pertussis vaccine and permanent neurological damage.⁷⁵ Between 1980 and 1986 alone, plaintiffs filed more than \$3.5 billion worth of damage claims against vaccine manufacturers.⁷⁶ As litigation expenses and damages awards increased, many vaccine manufacturers increased prices or ceased producing vaccines altogether.⁷⁷ In 1985, the Centers for Disease Control and Prevention (CDC) reported that U.S. stockpiles of some vaccines were below safe levels.⁷⁸ At that point, only two companies produced the DPT vaccine, and only one company manufactured the vaccine for polio.⁷⁹

Starting in the 1970s, the American Academy of Pediatrics (AAP) – an advocacy organization dedicated to the health and well-being of children and adolescents – took the position that tort litigation was a threat to pediatric immunization.⁸⁰ One of the seminal cases the AAP cited as an example of this threat was *Johnson v. American Cyanamid Co.*⁸¹ The plaintiff in this case alleged that he had been injured by the Sabin polio vaccine, but he claimed that he would not have been injured if his daughter – from whom he contracted polio – had received the Salk version of the vaccine instead.⁸² The Salk vaccine consisted of an injected dose of inactivated virus, while the Sabin vaccine was a preparation of attenuated virus administered

⁷⁴ *Id.*

⁷⁵ Copland & Howard, *supra* note 63, at 11.

⁷⁶ Brandon L. Boxler, Note, *What To Do With Daubert: How to Bring Standards of Reliable Scientific Evidence to the National Vaccine Injury Compensation Program*, 52 WM. & MARY L. REV. 1319, 1334 (2011).

⁷⁷ Ridgway, *supra* note 71, at 61.

⁷⁸ *Id.*

⁷⁹ Elizabeth A. Breen, *One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 316 (1998).

⁸⁰ Ridgway, *supra* note 71, at 61.

⁸¹ 718 P.2d 1318 (Kan. 1986).

⁸² *Id.* at 1323.

orally.⁸³ At the time, most public and private health organizations preferred the Sabin vaccine because it was easier to administer and there was evidence suggesting that it conferred longer-lasting immunity.⁸⁴ In addition, the defendant manufacturer was making the Sabin vaccine at the government's request.⁸⁵ Nonetheless, the Kansas jury awarded the plaintiff \$10 million in compensatory damages and ordered the vaccine manufacturer to pay \$8 million in punitive damages.⁸⁶ The verdict was upheld by an intermediate appellate court before finally being overturned by the Kansas Supreme Court.⁸⁷ Although all damages were eventually set aside, the manufacturer of the Sabin polio vaccine spent several years and millions of dollars defending the suit. In addition, the plaintiff was never compensated for his injuries that in all likelihood were caused by the Sabin vaccine. This case made it clear to many that the current situation was detrimental to both vaccine manufacturers and to those who were injured by vaccines.

Calls for reform began before the final resolution of the *Johnson* case. Appearing as an amicus in a Fifth Circuit case decided in 1974, the AAP argued that warnings about the adverse effects of immunization serve no useful purpose once epidemiologists have mandated universal vaccination.⁸⁸ Writing for the Fifth Circuit in that case, Judge John Minor Wisdom suggested that losses from unavoidable injuries caused by vaccines should be borne by the manufacturer as a cost of doing business and passed on to the public in the form of price increases.⁸⁹ The following year, Dr. Richard Krugman made the same proposal in the pediatric literature, and he recommended the establishment of a “no-fault coverage” system for vaccines.⁹⁰

⁸³ *Id.* at 1320.

⁸⁴ *Id.* at 1321.

⁸⁵ *Id.* at 1322.

⁸⁶ William M. Brown, *Déjà Vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 *BRANDEIS L.J.* 1 (2001).

⁸⁷ *Id.*

⁸⁸ *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1293 (5th Cir. 1974).

⁸⁹ *Id.* at 1294.

⁹⁰ Ridgway, *supra* note 71, at 61.

Finally, in 1985, Senator Paula Hawkins (R-FL) and Representative Henry Waxman (D-CA) introduced the National Childhood Vaccine Injury Act.⁹¹ The Act was intended to address two overriding concerns that Congress had about United States vaccination programs: 1) the instability of vaccine supplies due to manufacturers' fears about tort liability, and 2) the inadequate and inconsistent nature of existing state tort remedies for individuals injured by mandatory vaccination.⁹² Congress passed the Act in 1986, and it has compensated individuals for vaccine-related injury or death since 1988.⁹³

B. The National Vaccine Injury Compensation Program⁹⁴

The Vaccine Injury Compensation Program is managed by the Health Resources and Services Administration, an agency within the Department of Health and Human Services. The Department of Justice and the Court of Federal Claims also play important roles in administering the program. The program is funded by a \$0.75 tax on each dose of taxable vaccine that is sold; vaccines that are considered "taxable" are clearly defined in the Internal Revenue Code.⁹⁵ The money that is collected from these taxes is stored in the Vaccine Injury Compensation Trust Fund.⁹⁶ Since the program first started compensating injured claimants in 1988, \$2,281,706,685.32 has been disbursed to petitioners and \$89,108,361.76 has been paid to cover attorney's fees and other legal costs.⁹⁷

If a person – usually a child – receives a vaccine and subsequently suffers injury or death, that person or a representative may be able to file a claim to receive money from the National

⁹¹ *Id.*

⁹² Breen, *supra* note 79, at 316.

⁹³ NATIONAL VACCINE INJURY COMPENSATION PROGRAM: DATA & STATISTICS, *supra* note 2.

⁹⁴ Unless otherwise noted, the information in this section was taken from HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WHAT YOU NEED TO KNOW ABOUT THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (2006), *available at* <http://www.hrsa.gov/vaccinecompensation/84521booklet.pdf>.

⁹⁵ 26 U.S.C. §§ 4131-4132.

⁹⁶ 26 U.S.C. § 9510.

⁹⁷ NATIONAL VACCINE INJURY COMPENSATION PROGRAM: DATA & STATISTICS, *supra* note 2.

Vaccine Injury Compensation Program. As a threshold requirement to file a claim, the effects of the injury from the vaccine must have either lasted for more than six months after the vaccine was administered, resulted in a hospital stay and surgery, or resulted in death. If the claimant suffered an injury, he or she must file a claim within three years of the first symptom of the injury. If the claimant died, a representative must file a claim within two years of the death or within four years of the first symptom of the vaccine-related injury from which the death occurred.

After a claim is filed, an official at the Health Resources and Services Administration reviews the medical information in the claim. This review is then sent to a lawyer at the Department of Justice who reviews the legal aspects of the claim and writes a report. At this point, the file is transferred to a special master at the Court of Federal Claims. Special masters are lawyers that have two primary functions: case management and decision-making.⁹⁸ As a case manager, the special master oversees the collection of evidence and sets a time frame for its submission.⁹⁹ There is no formal discovery as a matter of right; the special master determines the format for taking evidence and hearing arguments based on the circumstances of each case and after consultation with the parties. As a decision-maker, the special master ultimately weighs the evidence in rendering a final, enforceable decision about whether the claim will be paid, and if so, how much money will be awarded.¹⁰⁰ If the special master decides to pay the claim, the petitioner must decide to either accept or reject the special master's decision. If either the petitioner or the Department of Health and Human Services is unsatisfied with the special

⁹⁸ U.S. COURT OF FEDERAL CLAIMS VACCINE PROGRAM/OFFICE OF SPECIAL MASTERS, <http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters> (last visited May 2, 2012).

⁹⁹ *Id.*

¹⁰⁰ *Id.*

master's resolution of the claim, either party may appeal to a judge of the Court of Federal Claims, then to the Court of Appeals for the Federal Circuit, and finally to the Supreme Court.

In order to receive an award from the Vaccine Injury Compensation Trust Fund, a petitioner must prove one of three things. First, the petitioner can prove that the first symptom of the injury occurred within the time period listed on the Vaccine Injury Table. The Vaccine Injury Table lists the vaccines that are covered by the compensation program, the injuries associated with each vaccine, and the maximum time period allowed between vaccine administration and the first symptom of the injury. Second, when an injury is not listed on the Table but is believed to have been caused by a vaccine that is covered by the program, the petitioner must use medical records or expert testimony to prove that the vaccine actually caused the injury. Finally, the petitioner has the option to prove that a vaccine caused an existing illness to get worse, meaning that the vaccine “significantly aggravated” a preexisting condition. If the petitioner is not claiming an injury covered by the Vaccine Injury Table, the special master must determine that the injury or aggravated condition did not result from any other possible causes. Although most petitioners choose the first alternative and claim injuries that are covered by the Table, about twenty-eight percent of the claims that the program receives concern “off-Table” injuries.¹⁰¹ Only thirteen percent of such petitioners, who have the burden of proving that the vaccine actually caused the injury, receive any compensation from the program. In addition, compensation awards are nearly three times lower for petitioners that claim “off-Table” injuries.¹⁰²

If a special master or a court decides to award the petitioner money from the Vaccine Injury Compensation Trust Fund, the petitioner is entitled to receive several different types of

¹⁰¹ Lainie Rutkow et. al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and its Influence During the Last Two Decades*, 111 PENN. ST. L. REV. 681, 720 (2007).

¹⁰² *Id.*

compensation. If the petitioner or the person on whose behalf the petition was filed was injured by a vaccine, the injured individual is entitled to recover a reasonable amount of money for past and future nonreimbursable medical, custodial care, and rehabilitation costs and related expenses. The petitioner may also receive up to \$250,000 for actual and projected pain and suffering, compensation for lost earnings, and reasonable attorneys' fees and other legal costs. If the person on whose behalf the petition was filed was killed by a vaccine, the petitioner is entitled to receive up to \$250,000 as a death benefit for the estate of the deceased, as well as reasonable attorneys' fees and other costs.

There are several other aspects of the National Vaccine Injury Compensation Program that are important to its function as a no-fault compensation scheme. First, a person who has been injured by a vaccine must exhaust all remedies available under the program before filing a civil lawsuit against the vaccine manufacturer. Second, eligibility for the National Vaccine Injury Compensation Program is not affected by the standard of care under which the vaccine was administered. For example, an injured person can still file a claim under the program if the vaccine's administrator was negligent or if the vaccine was administered for an "off-label" use. Third, the program relies on the Vaccine Adverse Event Reporting System (VAERS) to monitor vaccines for possible side effects. VAERS is a national vaccine safety surveillance program that is co-sponsored by the FDA and the CDC.¹⁰³ Anyone can file a VAERS report, including health care providers, manufacturers, and vaccine recipients. More than 30,000 VAERS reports are filed annually, with 10-15 percent of those reports classified as serious.¹⁰⁴

¹⁰³ ABOUT THE VAERS PROGRAM, <http://vaers.hhs.gov/about/index> (last visited May 2, 2012).

¹⁰⁴ Copland & Howard, *supra* note 63, at 12.

C. Evaluating the National Vaccine Injury Compensation Program

1. *Successes and Failures*

In the more than 25 years since the National Childhood Vaccine Injury Act was passed, many scholars have analyzed the extent to which the Act has achieved its purposes. In some respects, the vaccine compensation program has been a success. During the first ten years after the program was implemented, early childhood immunization rates improved and wholesale vaccine prices decreased.¹⁰⁵ Between 1990 and 1999, no commercial vaccine manufacturer ceased production, and there were no serious vaccine shortages in the United States.¹⁰⁶ In addition, large vaccine injury awards in state courts completely disappeared.¹⁰⁷ According to one commentator writing just before the turn of the century, “[t]he pharmaceutical industry has been vigorous in developing vaccines against diseases for which no vaccines exist, in creating combination vaccines, and in reengineering existing vaccines using biotechnology. . . . Since the inception of the program, measureable improvements have occurred in both vaccine access and utilization for U.S. children.”¹⁰⁸

Despite the early successes of the vaccine compensation program, some critics have argued that the Act has failed to adequately facilitate petitioners’ recovery for vaccine-related injuries.¹⁰⁹ In support of this contention is the fact that more than two-thirds of claims filed under the Act are ultimately dismissed.¹¹⁰ Injured individuals who are denied compensation under the Act generally remain uncompensated,¹¹¹ especially after the Supreme Court decided last year that the Act completely preempts state-law design defect claims against vaccine

¹⁰⁵ Ridgway, *supra* note 71, at 76.

¹⁰⁶ *Id.* Vaccine stockpiles maintained by the U.S. government were tapped only twice between 1988 and 1999, each time because of short-term production problems. *Id.*

¹⁰⁷ *Id.* at 77.

¹⁰⁸ *Id.*

¹⁰⁹ Breen, *supra* note 79, at 320.

¹¹⁰ *Id.*

¹¹¹ *Id.*

manufacturers.¹¹² Critics of the Act have also taken issue with the Vaccine Injury Table and the heightened causation requirement for petitioners who have suffered “off-Table” injuries. For example, a petitioner may be able to demonstrate that she suffered an injury listed on the Table, but she may not be able to prove that the injury occurred within the exact time period required by the Table.¹¹³ Without this proof, the petitioner has an “off-Table” injury and must establish causation by demonstrating: 1) a medical theory causally connecting the vaccination and the injury; 2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and 3) a showing of a proximate temporal relationship between vaccination and the injury.¹¹⁴

2. *Proposals to Improve the Program*

The process by which a petitioner demonstrates and a special master decides whether a vaccine caused the petitioner’s injury is one of the most controversial issues surrounding the National Vaccine Injury Compensation Program. Some critics have argued that the standard of proof for establishing causation is too strict and that the program would be more successful if the standard were relaxed.¹¹⁵ Betsy J. Grey, a professor at the Sandra Day O’Connor College of Law at Arizona State University, has argued that the strictness of the causation standard should depend on the primary objective of the compensation program.¹¹⁶ If the primary objective of the program is to “encourage widespread vaccination of the population by ensuring that vaccines are not incorrectly blamed for causing injury,” the causation standard should be more stringent, so

¹¹² *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011).

¹¹³ Breen, *supra* note 79, at 327.

¹¹⁴ *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

¹¹⁵ Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMIN. L. REV. 785, 846 (2011); Betsy J. Grey, *The Plague of Causation in the National Childhood Vaccine Injury Act*, 48 HARV. J. ON LEGIS. 343 (2011). There are three entities that have the power to control standards of proof under the National Vaccine Injury Compensation Program: 1) Congress, in its ability to amend the statute; 2) HHS, in its ability to amend the Vaccine Injury Table; and 3) the Federal Circuit, in its ability to interpret the Act and oversee the implementation of the program. Grey, *supra*, at 346.

¹¹⁶ Grey, *supra* note 115, at 348.

that only injuries actually caused by vaccines will be compensated.¹¹⁷ If the primary objective of the program is to “ensure adequate vaccine supplies by minimizing liability against manufacturers and administrators,” the causation standard should be more relaxed, so that individuals injured by vaccines are compensated without having to resort to the tort system.¹¹⁸ Advocating the primacy of the latter objective, Professor Grey has argued that the concept of “causation” in the National Vaccine Injury Compensation Program be replaced with the concept of “association.”¹¹⁹ She proposes that the risk of scientific uncertainty be shifted away from the petitioner to a greater extent than is currently found in the common law system; the program – not the petitioner – should shoulder most of the risk that the petitioner’s injury was not actually caused by a vaccine.¹²⁰ Under this new concept of “association,” a petitioner would only have to prove the theoretical capacity of the vaccine to cause her particular type of injury.¹²¹

In contrast to Professor Grey’s proposal, at least one critic has suggested that the procedures for proving causation under the National Vaccine Injury Compensation Program should be *more* rigorous, to ensure that compensation decisions are based on reliable scientific evidence. The special masters at the Court of Federal Claims have a significant amount of freedom to admit and weigh evidence, and the master’s final decision will only be overturned if it is arbitrary and capricious.¹²² When Congress passed the National Childhood Vaccine Injury Act, it provided very little guidance to the special masters besides charging the Court of Federal Claims with promulgating “flexible and informal standards of admissibility of evidence.”¹²³ The court responded to this charge by creating the Vaccine Rules, which specifically state that special

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² Boxler, *supra* note 76, at 1338, 1341.

¹²³ 42 U.S.C. § 300aa-12(d)(2).

masters “will not be bound by common law or statutory rules of evidence.”¹²⁴ Even the Federal Circuit has recognized that “[c]ausation in fact under the Vaccine Act is . . . based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules.”¹²⁵ In order to ensure that special masters have the power to exclude evidence and testimony from their courtrooms and base their decisions on reliable scientific information, Congress or the Supreme Court could declare that special masters are bound by the evidentiary framework set forth in *Daubert v. Merrill Dow Pharmaceuticals, Inc.*¹²⁶ This framework would allow special masters to exclude evidence or testimony that is irrelevant, unreliable or scientifically invalid.¹²⁷

These proposals for reforming the National Vaccine Injury Compensation Program are relevant to policymakers considering a similar no-fault compensation scheme for prescription drugs. Understanding the successes and failures of the vaccine program will enable Congress to design a system for drugs that duplicates the successful aspects of the program while avoiding some of the problems it has faced.

¹²⁴ VACCINE R. FED. CL. 8(b)(1).

¹²⁵ Knudsen *ex rel.* Knudsen v. Sec’y of Health & Human Services, 35 F.3d 543, 548 (Fed. Cir. 1994).

¹²⁶ Boxler, *supra* note 76. The Supreme Court in *Daubert* described four factors that a court should consider to determine whether expert testimony constitutes “good science”: 1) whether the scientific theory or technique has been tested; 2) whether the theory or technique has been subjected to peer review and publication; 3) the technique’s known or potential rate of error; and 4) the extent to which the theory or technique has been accepted by the relevant community. *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-94 (1993).

¹²⁷ U.S. Supreme Court Justice Stephen Breyer has emphasized the necessity of basing compensation decisions on reliable scientific evidence:

The importance of scientific accuracy . . . reach[es] well beyond the case itself. A decision wrongly denying compensation in a toxic substance case, for example, can deprive not only the plaintiff, say a worker, of warranted compensation, but can discourage other, similarly situated workers from even trying to obtain compensation and encourage the continued use of a dangerous substance. On the other hand, a decision wrongly granting compensation, while of immediate benefit to the plaintiff worker, can . . . improperly force abandonment of the substance. This, if the decision is wrong, will improperly deprive the public of what can be far more important benefits – say those surrounding a drug that cures many while subjecting to less serious risk a few.

Stephen Breyer, *The Independence of Science and Law*, 82 JUDICATURE 24, 25 (1998).

D. International Examples of No-Fault Systems to Compensate Drug-Related Injury and Death

If the United States establishes a no-fault compensation system for prescription drugs, it will not be the first country to do so. Several other countries had implemented no-fault schemes to compensate drug-related injury and death before Congress passed the National Childhood Vaccine Injury Act in 1986.¹²⁸

1. Germany

West Germany implemented a no-fault compensation system after the thalidomide disaster of the early 1960s.¹²⁹ The German system, established in 1976, was intended to compensate personal injury and death resulting from defective drugs, but it also compensates injuries resulting from non-negligent manufacturing defects and failures to warn.¹³⁰ An individual will be compensated if that individual has been injured by a prescription drug “whose harmful effects in the course of its prescribed use objectively exceeded acceptable limits in the light of medical scientific knowledge.”¹³¹ Unlike petitioners under the National Vaccine Injury Compensation Program, a petitioner under the German program forfeits all protection by using a drug in a way that does not conform to the manufacturer’s instructions.¹³² In addition, the petitioner is accountable for any part of his injury that he may have caused, in accordance with the common law principle of comparative negligence.¹³³

¹²⁸ John G. Fleming, *Drug Injury Compensation Plans*, 30 AM. J. COMP. L. 297 (1982).

¹²⁹ Thalidomide was a sedative drug introduced in the late 1950s that was used to treat morning sickness in pregnant women. Emma Wilkinson, *Thalidomide survivors to get £20m*, BBC, Dec. 23, 2009, <http://news.bbc.co.uk/2/hi/8428838.stm>. It was withdrawn in 1961 after being found to cause severe birth defects in children born to women who had taken the drug. *Id.*

¹³⁰ Fleming, *supra* note 128, at 300-01.

¹³¹ Arzneimittelgesetz, 24 August 1976, § 84.

¹³² Fleming, *supra* note 128, at 301.

¹³³ *Id.*

2. Sweden

Another no-fault compensation scheme for prescription drugs was established in Sweden in 1978.¹³⁴ The Swedish Pharmaceutical Insurance was the result of a voluntary agreement between the pharmaceutical industry and a consortium of insurance companies.¹³⁵ Like the National Vaccine Injury Compensation Program, the system is funded entirely by taxes paid by pharmaceutical companies.¹³⁶ If a patient takes a drug and subsequently suffers a significant disability – measured by the extent of bodily injury and/or the amount of time the patient spent away from work – she fills out a form with the aid of her physician and submits it to her insurance company.¹³⁷ The form and all of the patient’s pertinent medical records are then reviewed by the insurer’s medical assessor and physician advisors, who determine whether there is a “preponderant probability” that the patient’s injury was caused by the drug she took.¹³⁸ If the patient disagrees with the insurance company’s decision, the case is referred to the Drug Injury Committee, which investigates and reports its findings with respect to the patient’s right to receive compensation.¹³⁹ Any disputes that persist are resolved through arbitration.¹⁴⁰ If the injured patient ultimately accepts compensation from the program, she subrogates all other remedies to the insurance company.¹⁴¹

¹³⁴ Jackson, *supra* note 10, at 226.

¹³⁵ *Id.* at 227.

¹³⁶ *Id.*

¹³⁷ *Id.* at 227-28.

¹³⁸ *Id.* at 227.

¹³⁹ *Id.*

¹⁴⁰ *Id.* 227-28.

¹⁴¹ *Id.* at 228.

IV. Establishing a No-Fault Compensation System for Prescription Drugs

A. Can policymakers rely on the National Vaccine Injury Compensation Program as a model?

In order to use the National Vaccine Injury Compensation Program as a model for a no-fault compensation system for prescription drugs, it is important to consider the similarities and differences between vaccines and drugs and compare and contrast the markets for each product. One of the most significant differences between vaccines and drugs is that vaccination is mandatory, but consuming a drug is a matter of individual choice.¹⁴² A major impetus behind the National Childhood Vaccine Injury Act was Congress's belief that people should be compensated if they are injured by a procedure that the government requires them to undergo. This rationale does not apply to prescription drugs because a sick or injured individual always has a choice about whether or not to take a drug. Even when this "choice" is really a choice between life and death, the government never requires a patient to take a drug the same way it requires people to get vaccinated.

Another difference between vaccines and drugs is the subset of the population to which these products are administered. Vaccines are given to healthy individuals, particularly children, who generally do not suffer from pre-existing conditions and constitute the healthiest age group in the United States. In contrast, prescription drugs are taken by individuals who are sick or injured, meaning that their health is substantially compromised before they are treated. This makes it much more difficult to establish a causal link between a prescription drug and an adverse event than it is to establish causation between a vaccine and a particular injury.¹⁴³ The heightened difficulty of determining causation when a patient claims to have been injured by a

¹⁴² Jacobi, *supra* note 26, at 1002.

¹⁴³ Copland & Howard, *supra* note 63, at 13.

prescription drug, as compared to when a patient claims a vaccine-related injury, must be taken into account when designing a no-fault compensation system for drugs.

Although there are several significant differences between vaccines and drugs, the similarities between the two products suggest that the National Vaccine Injury Compensation Program could be relied on as a model for a no-fault compensation system to replace certain drug product liability causes of action. Drugs, like vaccines, have enormous public health value.¹⁴⁴ In addition, the FDA is extensively involved in regulating the testing, development, and marketing of both drugs and vaccines.¹⁴⁵ Finally, experts have recognized that it is impossible to attain absolute safety for drugs and vaccines, but these unavoidably unsafe products are absolutely necessary in modern society.¹⁴⁶ Patients benefit from a robust drug market characterized by innovation and price competition, so the government should ensure that drug companies are not withdrawing from the market to avoid skyrocketing litigation costs and damages awards. Over the years, there have been numerous examples of prescription drug shortages that parallel the vaccine shortages of the 1980s. For example, concerns about liability for drug-related injuries have contributed to drug shortages and stifled innovation in the market for contraceptives;¹⁴⁷ no fundamentally new contraceptive drugs have been introduced in the United States since the 1960s.¹⁴⁸ While the differences between drugs and vaccines indicate that a no-fault compensation scheme for drugs would have to include some elements that are drug-specific, the

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ Brown, *supra* note 86, at 32. “Pharmaceutical companies have moved out of contraceptive research because of fear of product liability lawsuits and particularly the enormous and seemingly standardless sums juries have awarded in punitive damages in such litigation.” *Id.* Other factors that have contributed to contraceptive drug shortages and the lack of innovation in this market include stringent toxicity tests required by the FDA, market saturation and limited profit potential, and the political problems associated with the perceived link between contraceptives and abortion. *Id.* at 34-38.

¹⁴⁸ *Id.* at 30.

similarities between the products suggest that the National Vaccine Injury Compensation Program is a good model for a new system that will compensate drug-related injuries.

B. The Prescription Drug Injury Compensation Program

A no-fault scheme to compensate individuals injured by prescription drugs would have four main goals.¹⁴⁹ First, the scheme would compensate individuals for injuries resulting from serious, unforeseen adverse events in a fair, timely and transparent manner. Second, the scheme would protect pharmaceutical manufacturers from skyrocketing litigation costs and damages awards by preempting state-law failure-to-warn claims. Third, by providing manufacturers with a greater amount of certainty about the post-market cost of producing a prescription drug, the scheme would promote greater innovation in U.S. drug markets. Fourth, by enabling more rigorous monitoring of adverse events caused by prescription drugs, the scheme would yield increased information that officials can use to improve the safety and effectiveness of drugs in our country.

1. Program Overview

The Prescription Drug Injury Compensation Program (“the Program”) would only apply to certain drugs that are sold in the United States. While the Program would not cover over-the-counter medications, it would apply to prescription drugs produced by both brand-name and generic manufacturers.¹⁵⁰ The FDA would be charged with developing and maintaining a list of drugs covered by the Program. It would be left for the FDA to decide whether the Program should be extended to cover “lifestyle drugs” – an imprecise category of medications that treat

¹⁴⁹ These goals are adapted from Copland & Howard, *supra* note 63, at 2.

¹⁵⁰ At least one commentator has suggested that a no-fault compensation system should only cover injuries caused by generic drugs because brand-name drug manufacturers “enjoy both a legal patent monopoly and exclusive access to clinical studies and post-marketing adverse drug reaction data.” Sarah C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 VAND. J. ENT. & TECH. L. 185, 213 (2010). However, because brand-name drug manufacturers are the only companies that develop and sell innovative new drugs, a compensation system that only applied to generic drugs would not promote innovation in U.S. drug markets.

non-life-threatening or superficial conditions such as baldness, impotence, and acne.¹⁵¹ While the National Vaccine Injury Compensation Program compensates petitioners for almost any injury – as long as the petitioner can prove that the injury was caused by a vaccine – the Prescription Drug Injury Compensation Program would be more limited in scope. Unless a drug has a significant public health benefit, such as stopping the spread of a dangerous communicable disease, the Program would not compensate individuals for any side effects they suffer after taking the drug if the FDA knew about those side effects and adequately described them on the drug’s label.¹⁵² Therefore, the Program would only compensate petitioners who suffer unforeseen adverse events.

In order for an individual to receive compensation from the Program, he would have to prove an actual injury – there would be no compensation for medical monitoring, as is sometimes available from the tort system. The injury must have been sustained after taking a covered drug for a disease or condition for which the drug was approved by the FDA; the petitioner would not recover from the Program if his injury resulted from off-label use of a drug. If an injured individual has taken a drug that is covered by the Program, any state-law failure-to-warn claims that he could bring against the drug’s manufacturer would be expressly preempted. A petitioner would only be able to file a lawsuit in the tort system after all of his appeals under the Program have been exhausted. The amount of money that a petitioner would be entitled to receive from the Program would vary depending on the severity of his injury, but the general

¹⁵¹ If one of the main goals of the compensation system is to incentivize the development and marketing of drugs that are beneficial to society, the FDA would have to determine whether “lifestyle drugs” fit this definition. Perhaps we want drug manufacturers to focus on developing life-saving drugs to treat serious conditions such as cancer or heart disease, or perhaps we feel just as strongly about encouraging the development of drugs that improve the quality of human life in more superficial ways.

¹⁵² Copland & Howard, *supra* note 63, at 12.

categories of injury-related expenses that would be covered are: medical expenses, lost wages, rehabilitation, and pain and suffering.

2. *Administration and Funding*

Similar to the National Vaccine Injury Compensation Program, the Prescription Drug Injury Compensation Program would be jointly administered by the Health Resources and Services Administration within the Department of Health and Human Services, the Department of Justice, and the Court of Federal Claims. The FDA would also play a very important role by creating and regularly updating the list of drugs that are covered by the Program. Initial compensation decisions under the Program would be made by special masters at the Court of Federal Claims, who serve the same function in the vaccine program. A petitioner who disagrees with the master's decision would have the option to appeal that decision to the Court of Federal Claims, then to the Federal Circuit, and finally to the Supreme Court.

The Program would be funded by a tax on covered prescription drugs. There are multiple ways to structure this tax. For one, rather than setting a flat tax rate for every pill that is sold, the Program could collect a percentage of the retail price of each drug. Therefore, the higher the retail price of a drug, the higher the tax on that drug. A more complicated way to structure the tax would be to collect higher taxes on drugs that cause more unforeseen adverse events, which are the drugs that cost the Program the most money. Of course, determining which drugs fall into this category is impossible *ex ante*, so the Program could start by setting tax rates on the basis of a pharmaceutical manufacturer's market share.¹⁵³ Over time, the Program could "risk adjust" a manufacturer's tax burden on the basis of the size of payouts to the users of its drugs, thereby encouraging manufacturers to improve the safety of their products.¹⁵⁴

¹⁵³ *Id.* at 15.

¹⁵⁴ *Id.*

3. *Demonstrating Causation in Fact*

One of the most difficult aspects of establishing the Prescription Drug Injury Compensation Program would be setting a causation standard that allows Program administrators to identify legitimate claims without placing an impossible burden on petitioners. To streamline the causation inquiry undertaken by special masters at the Court of Federal Claims, the statute creating the Program should explicitly state that masters are bound to apply the Supreme Court's *Daubert* framework to determine the reliability of scientific evidence. In addition, proceedings before a special master would function like a trial before a judge; evidence would be presented according to the Federal Rules of Evidence, and expert witnesses would be sequestered until they testify.¹⁵⁵ In order to receive compensation from the Program, a petitioner would have to demonstrate that it is more likely than not that a prescription drug caused the adverse event for which she is seeking compensation. The special master – ideally a lawyer with significant training and experience in medicine or science – would make the initial determination of whether the petitioner satisfied the causation standard. Leaving this decision to the special master avoids the problem of relying on lay juries, who are often confused by expert witnesses and have difficulty understanding the complicated scientific theories presented at trial.¹⁵⁶ Using the Prescription Drug Injury Compensation Program to establish a framework for semi-formal adjudicative proceedings before qualified special masters would ideally ensure more predictability and consistency than drug manufacturers currently receive from the tort system.

¹⁵⁵ When special masters hear claims under the National Vaccine Injury Compensation Program, the Federal Rules of Evidence do not apply. VACCINE R. FED. CL. 8(b)(1). In addition, expert witnesses are not sequestered until they testify; in fact, they generally sit at counsel table throughout the entire proceeding. Meyers, *supra* note 115, at 811.

¹⁵⁶ See text accompanying notes 19-21.

V. Conclusion

Congress should implement a no-fault compensation system, modeled after the National Vaccine Injury Compensation Program, which will award money to patients who suffer unexpected adverse events as a result of taking a prescription drug. Most importantly, this compensation system should preempt state-law failure-to-warn claims against prescription drug manufacturers. Without having to face incredible uncertainty about the amount of damages awards or litigation expenses a drug will incur after it is sold to the public, pharmaceutical manufacturers would have greater incentives to invest in the development of new and innovative drugs that would greatly benefit patients. At the same time, patients who take a prescription drug and suffer a serious injury that was not foreseen by the drug's manufacturer or the FDA will be compensated, so long as they can demonstrate that the drug was the cause of their injury. Society as a whole would benefit from the elimination of deadweight loss associated with failure-to-warn litigation, and the risk of unexpected injuries caused by prescription drugs would be efficiently spread among drug manufacturers and patients. Mounting evidence suggests that Congress should implement a no-fault compensation system to replace failure-to-warn claims against prescription drug manufacturers, and the National Vaccine Injury Compensation Program provides an excellent model that can be adapted to meet the specific needs of participants in the market for prescription drugs.